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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/923,243 | 08/03/2001 | Gavin MacBeath | H00498/70162 TJO | 9118 |

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,243

Applicant(s)

MACBEATH ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 28-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment filed on May 30, 2003 has been received, entered into record and considered. The following information provided in the amendment affects the instant application:

1. Claim 35 is amended.
2. Claims 1-27 and 48-104 are cancelled.
3. Currently, claims 28-47 are pending and under examination.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 28-33, 36, 41, 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US 5496452) in view of Charych et al. (US 2002/0055125).

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Hill et al. teach immobilizing enzyme on a biosensor to measure toxins in the sample. (See abstract) Hill et al. teach coupling enzymes to BSA through carbohydrate moieties which have been previously been oxidized with NaIO_4 . (Col. 3, line 8-25) Hill et al. disclose that BSA as a linker offers the advantages of avoiding direct amino acid attachment to the solid support, in decreasing enzyme denaturation, and thus preserve the function and proper folding of the enzyme for binding of the target in interest. Supra. Furthermore, the BSA linker also provides advantages of creating a protein cushion which protects the enzyme from other unnecessary manipulation in the test system. Supra. However, Hill et al. do not specifically teach an array with the density of 1000-1500 spots per cm^2 and interacting the BSA with an antibody.

Charych et al. teach a proteomic microarray assay having the density of spots from 1-5000 spots per cm^2 . (See Section 0069) The solid support materials include, glass, polymers, metal. (Section 0037) Charych et al. also disclose using antibody specific for the target protein as a positive control or differential comparison. (See Section 0126) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method Hill et al. with the device and coupling target specific antibody as taught by Charych et al. since an efficient throughput analysis is of great demand in studying protein complex field. (See Section 0007)

4. Claims 34, 35, 37-40 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hill et al. in view of Charych et al., as applied to claims 28-33, 36, 41 above, and further in view of Kato et al. (US 4507234)

Both Hill and Charych et al. references have been discussed but do not explicitly teach using covalent binding to couple with BSA and the proteins. Kato et al. teach coupling the cytotoxic agents with BSA and antibody to increase the selectivity and efficiency of the agents. (Col. 1, line 22-30) The covalent coupling include Schiff linkage, Michael addition, disulfide bond, transacylation. (See formula I, II, II-1 and II-2 from Col. 5- Col. 14) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have

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provided Hill and Charych et al. with coupling methods as taught by Kato et al. to increase the selectivity and efficiency on the binding of the target molecules to the affinity proteins. Supra.

5. Claim 42 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Hill et al. in view of Charych et al., as applied to claims 28-33, 36, 41 above, and further in view of Patron et al. (USP 2001/0041349).

Hill and Charych et al.'s references have been discussed but fails to specifically teach using poly-histidine-metal interaction as the protein/BSA binding method. Patron et al. teach using poly-histidine tag to bind to metals for purification purpose in a protein microarray. (See Figure 1; Section 0039, line 5-10) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the reference of Charych et al. with the poly-histidine tag as taught by Patron et al. to increase the purity and reduce the contaminants of the protein microarray. Supra.

Response to Applicant's Argument

6. Applicant's arguments with respect to claim 28 to 42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9434 for regular communications and 703-746-9434 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.


Jacob Cheu



Examiner

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August 8, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

08/11/03